REMARKS

I. Claim Status

Claims 17, 19-27, 29, 30, and 77-79 are currently pending and stand rejected. Claims 24 and 25 have been cancelled without prejudice or disclaimer and retaining the right to represent in a subsequent divisional or continuing application.

Claims 17, 23, 29, and 30 have been amended.

Claim 17 has been amended to recite "wherein the compression molding is carried out using a compression molding machine in which a lubricant selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, stearyl alcohol, sodium stearyl fumarate and sucrose fatty acid ester is previously applied on a surface of punch and die," and finds support in the Specification as filed at original claim 24.

Claims 17 and 23 have been amended to recite "selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, stearyl alcohol, sodium stearyl fumarate and sucrose fatty acid ester," and finds support in the Specification as filed at original claim 25.

Claims 29 and 30 have been amended to define the ratio as a compounding ratio. Support for this amendment comes from the Specification as filed at page 11, lines 9-21, and at page 14.

No new matter has been added.

II. Claim Rejections

a) 35 U.S.C. § 112, First Paragraph

Claims 29 and 30 stand rejected as failing to comply with the written description requirement. The Examiner contends that there is no teaching of "the ratio of D-mannitol" or "the ratio of the disintergrator," and that these are new matter.

The Examiner notes that the Specification teaches compounding ratios of D-mannitol and a disintegrator, and has suggested that the same language be used in the claims. Without conceding the correctness of the Examiner's position or the need for amendment, claims 29 and 30 have been amended to add the term "compounding" in accordance with the Examiner's suggestion. Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 17, 19-27, 29, 30, and 77-79 stand rejected as failing to comply with the written description requirement. The Examiner contends that the limitation in claim 17, "the ratio of the fine granules," constitutes new matter.

The Examiner notes that the Specification teaches compounding ratios of the fine granules, and has suggested the same language be used in the claims. Without conceding the correctness of the Examiner's position or the need for amendment, claim 17 has been amended to add the term "compounding" in accordance with the Examiner's suggestion. Applicants respectfully request reconsideration and withdrawal of this rejection.

b) 35 U.S.C. § 103(a)

Claims 17, 20, 21, 23, and 25-27 stand rejected as being obvious over Lech et al. (U.S. Patent No. 5,681,577, "Lech"). The Examiner contends that Lech teaches a method of making a cold/sinus preparation which comprises wet granulation of the active agents and an adsorbent; namely, silicon dioxide. The Examiner further contends that Lech teaches the adsorbent to comprise about 50% to about 85% of the adsorbable composition, which translates to a ratio of actives to adsorbate being approximately 1:10 to 1:1. The Examiner cites Example III, which teaches that the actives and adsorbents make up 25% (i.e., 25% + 3.0% + 20.75%) of the total weight of the preparation. Example III also teaches that, once the drug adsorbate is created, additional excipients including sweeteners, colorants, and flavorings are blended with the drug adsorbate, and then the particular lubricant, magnesium stearate, is added to the mixture and subsequently compressed into tablets. The Examiner further states that the actives taught by Lech are water-soluble, as evidenced by the stop of dissolving the actives in water prior to the wet granulation step, and citing as a preferred active agent diphenhydramine HCl which has a solubility of 1g/1mL. The Examiner further states that Lech teaches incorporating particular excipients, including disintegrants such as microcrystalline cellulose and other cellulose derivatives in order to aid in the tableting and oral administration processes, as well as including mannitol as a tableting agent. The Examiner goes on to note that D-mannitol and mannitol are analogous, and that mannitol has a specific surface area of $0.60 m^2/g$ and has a particle-size distribution of between about 60 and 180 microns.

The Examiner concedes that while Lech does not require a disintegrant, Lech provides motivation for including a disintegrant because Lech teaches that a disintegrant aids in the tableting and oral administration processes. The Examiner concludes that a practitioner would have reasonably expected a tablet comprising a drug adsorbate, D-mannitol, and a disintegrant for oral administration; and, therefore, it would have been obvious to include a disintegrant as suggested by Lech. Applicants respectfully traverse.

Claim 24 was found not to be obvious in view of Lech. Without conceding the correctness of the Examiner's position or the need for amendment, claim 17 has been amended to incorporate the limitation found in claim 24. Claims 20, 21, 23, 26, and 27 all depend from amended claim 17 and are, therefore, also not obvious in view of Lech. Claim 25 has been cancelled without prejudice or disclaimer. Applicants therefore respectfully request reconsideration and withdrawal of this rejection.

Claims 19 and 77-79 stand rejected as obvious over Lech in view of Remington (*The Science and Practice of Pharmacy*). The Examiner contends that Lech teaches the elements discussed above, including disintegrants such as microcrystalline cellulose and other cellulose derivatives. The Examiner concedes that Lech is silent as to the particular disintegrants of crospovidone, low-substituted hydroxypropylcellulose, croscarmellose sodium and carboxymethylcellulose. The Examiner concludes that Remington teaches well-known disintegrants used in the preparation of tablets, including crospovidone and celluloses such as croscarmellose and carboxymethylcellulose.

The Examiner also states that both references, Lech and Remington, teach tablets and conventional tableting methods containing conventional tablet ingredients. The Examiner concludes that it would have been obvious to substitute one disintegrant for another because they are art-recognized equivalents and their substitution would achieve the result of producing a tablet. Applicants respectfully traverse.

Claim 24 has been found to be not obvious over Lech in view of Remington. Without conceding the correctness of the Examiner's position or the need for amendment, claim 17 has been amended to incorporate the limitation found in claim 24.

Claims 19 and 77-79 either directly or indirectly depend from amended claim 17. Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants believe the pending application is in condition for allowance, and allowance is earnestly solicited. If there are any remaining issues which the Examiner believes can be resolved through a Supplemental Amendment or an Examiner's Amendment, the Examiner is invited to contact the undersigned at the telephone number indicated below.

Dated: May 2, 2008

Respectfully submitted,

By 

Louis J. DelJuidice
Registration No.: 47,522
DARBY & DARBY P.C.
P.O. Box 770
Church Street Station
New York, New York 10008-0770
(212) 527-7700
(212) 527-7701 (Fax)
Attorneys/Agents For Applicant